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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,660	01/20/2004	You-Lo Hsieh	18062G-005120US	3387

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EXAMINER
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NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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06/15/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/761,660

**Applicant(s)**

HSIEH ET AL.

**Examiner**

David M. Naff

**Art Unit**

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>6/5/07</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

An amendment of 3/16/07 amended claims 1, 20, 29, 42 and 43.

Claims examined on the merits are 1-43, which are all claims in the application.

5       The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

Claims 42 and 43 are rejected under 35 U.S.C. 102(a) as being anticipated by Jia et al (AL on 1449).

10       The claims are drawn to an insoluble nanofiber comprising a polymer and a biological material.

Jia et al disclose enzyme-carrying polymeric nanofibers prepared via electrospinning. The enzyme is bound to the nanofiber as shown by scheme 1 (page 1028, left col). Various synthetic or natural polymers  
15 have been electrospun into fibers with diameters below 100 nm.

Nanofibers are prepared having a diameter of 120 nm (page 1029, left col, under "Results and Discussions"). The nanofibers are prepared from polystyrene (page 1028, right col, under "Electrospinning").

The enzyme-containing nanofibers disclosed by Jia et al are  
20 inherently insoluble and porous as claimed, and are the same as the presently claimed insoluble nanofiber. The polystyrene is a polymer and the enzyme is a biological material as claimed.

***Response to Arguments***

The amendment urges that the nanofibers of Jia et al do not  
25 contain a plurality of pores. However, it appears the nanofibers of

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Jia et al would contain a plurality of pores within the definition of pores in the present specification (page 8, lines 8-9). There is inadequate evidence that such pores are not contained by the nanofibers of Jia et al. The 37 CFR 1.131 Declaration of 3/26/07 fails to antedate Jia et al since the evidence in the declaration is directed to ultra-fine fibrous membranes rather than nanofibers containing a biological material as presently claimed.

***Claim Rejections - 35 USC § 103***

Claims 1-10, 12-18, 20-31, 38, 39, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jia et al in view of Wendorff et al (6,790,528 B2).

The claims require a nanofiber having a plurality of nanopores, and containing a first polymer and a biological material.

Jia et al is described above.

Wendorff et al disclose producing porous nanofibers having a diameter of 20-4000 nm by electrospinning (abstract and col 2, lines 11-31, and col 3, lines 47-57). The nanofibers can be used as a carrier for a catalyst, or as a biomaterial. The fibers can be prepared from a blend of polymers (col 2, lines 32-40) that can be synthetic and natural. The fibers can be subjected to surface modification (col 3, lines 36-46). The fibers can be used for making fabrics for use as a catalyst carrier (col 7, lines 29-36). The fibers have a very large surface area (col 2, lines 11-13).

It would have been obvious to provide the nanofibers of Jia et al with nanopores to obtain a very large surface area as suggested by

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Wendorff et al producing porous nanofibers having a very large surface area for use as a catalyst carrier. The conditions of dependent claims would have been obvious in view of the disclosures of the references. Jia et al disclose that fibers of diameter below 100 nm have been produced, and it would have been obvious to select optimum fiber diameter range as in claim 12 within the range disclosed by Wendorff et al. The diameter of nanopores in claims 13-16 would have depended on intended use of the fibers, and selecting a particular diameter for a certain use would have been obvious. The 4-nitro-phenyl chloroformate (NPC) used in scheme 1 of Jia et al is a linker as in claim 10. Wendorff et al disclose polymer blends (col 2, line 33), and a second polymer as in claim 20 would have been obvious. Proportions of first and second polymers as in claims 21-25 would have been a matter of individual preference within the skill of the art. A fabric as in claims 38 and 39 is suggested by Wendorff et al (col 7, line 29).

Wendorff et al is a 371 of a PCT published as WO02/16680 on 2/28/02. This date is prior to the earliest date of 11/12/02 which the present application relies on for priority.

#### ***Response to Arguments***

The 1.131 Declaration does not antedate Wendorff et al since the evidence relied on is directed to membranes, and not to nanofibers as presently claimed.

***Claim Rejections - 35 USC § 103***

Claims 11 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Vann (6,573,089 B1).

5        The claims require a linker which can be polyethylene glycol (PEG) for attaching the biological material to the nanofiber.

Vann discloses using polyethylene glycol as a linker for attaching a biological molecule to a fiber (col 33, lines 61-62).

10        When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to use PEG as a linker to attach the biological material to the nanofibers as suggested by Vann.

***Response to Arguments***

15        The amendment urges that the references presently applied do not suggest nanofibers containing a plurality of nanopores. However, the references applied above disclose suggest nanofibers containing a plurality of nanopores. The declaration does not obviate the rejection for reasons set forth above.

***Claim Rejections - 35 USC § 103***

20        Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Smith et al (6,821,479 B1).

The claim requires the polymer to be cross-linked.

Smith et al disclose forming a fiber having a diameter of 0.3 nm to 25 microns. The fiber can be cross-linked (col 16, line 7).

When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to cross-link the polymer used to form the nanofibers as suggested by Smith et al.

***Response to Arguments***

5       The amendment urges that the references presently applied do not suggest nanofibers containing a plurality of nanopores. However, the references applied above disclose suggest nanofibers containing a plurality of nanopores. The declaration does not obviate the rejection for reasons set forth above.

10                   ***Claim Rejections - 35 USC § 103***

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Lockhart (6,974,673 B2).

15       The claim requires using PAA (polyacrylic acid) as a linker to attach the biological material to the nanofiber.

Lockhart discloses (col 9, line 44) using polyacrylic acid as a linker for attaching a molecular constituent to a fiber (col 2, lines 20, 31-43 and 50).

20       When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to use PAA as a linker to attach the enzyme to the nanofibers as suggested by Lockhart disclosing using PAA as a linker to attach a molecular constituent to a fiber.

***Response to Arguments***

The amendment urges that the references presently applied do not suggest nanofibers containing a plurality of nanopores. However, the references applied above disclose suggest nanofibers containing a plurality of nanopores. The declaration does not obviate the rejection for reasons set forth above.

***Claim Rejections - 35 USC § 103***

Claims 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1-10, 12-18, 20-31, 38 and 39 above, and further in view of Chu et al (6,790,455 B2).

The claims require a membrane comprising the nanofiber containing a biological material and polymer.

Chu et al disclose (col 19, lines 18-20, col 22, lines 58-62, col 23, lines 47-50, and col 24, line 6) producing a membrane containing nanofibers for cell storage and delivery systems.

When providing the nanofibers of Jia et al with nanopores as set forth above, it would have been obvious to produce a membrane containing the nanofibers as suggested by Chu et al to obtain the expected function of the membrane.

***Response to Arguments***

The amendment urges that the references presently applied do not suggest nanofibers containing a plurality of nanopores. However, the references applied above disclose suggest nanofibers containing a plurality of nanopores. The declaration does not obviate the rejection for reasons set forth above.



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***Claim Rejections - 35 USC § 103***

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 32-35 above, and further in view of Vann.

5       The claim requires PEG as a linker.

Vann is described above.

When providing the nanofibers of Jia et al with nanopores and providing a membrane comprising the nanofibers as set forth above, it would have been obvious to use PEG as a linker to attach the  
10   biological material to the nanofibers as suggested by Vann.

***Response to Arguments***

The amendment urges that the references presently applied do not suggest nanofibers containing a plurality of nanopores. However, the references applied above disclose suggest nanofibers containing a  
15   plurality of nanopores. The declaration does not obviate the rejection for reasons set forth above.

***Claim Rejections - 35 USC § 103***

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 32-35 above, and further in  
20   view of Lockhart.

The claim requires PAA as a linker.

Lockhart is described above.

When providing the nanofibers of Jia et al with nanopores and providing a membrane comprising the nanofibers as set forth above, it  
25   would have been obvious to use PAA as a linker to attach the enzyme to

the nanofibers as suggested by Lockhart disclosing using PAA as a linker to attach a molecular constituent to a fiber.

***Response to Arguments***

The amendment urges that the references presently applied do not suggest nanofibers containing a plurality of nanopores. However, the references applied above disclose suggest nanofibers containing a plurality of nanopores. The declaration does not obviate the rejection for reasons set forth above.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff

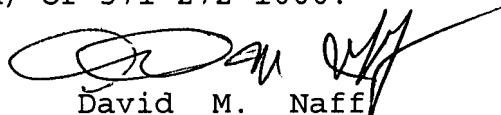
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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925.

5 The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained  
10 from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-  
15 9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David M. Naff  
Primary Examiner  
Art Unit 1657

20 DMN  
6/11/07